

REMARKS

Claim 3 has been cancelled without prejudice, and claims 43-55 have been added. Thus, upon entry of the amendments, claims 2, 4-11, and 43-55 will be pending. The newly added claims are supported by the specification as filed. For example, clause a) of claims 43 and 53, as well as newly added claim 44, are supported by page 6, line 20 to page 7, line 4. Clause b) of claims 43 and 53, and claim 45 are supported, for example, by the disclosure at page 7, lines 14-18. Clause c) of claims 43 and 53, as well as claim 46 are supported, for example, by the disclosure at page 7, lines 14-15. Clause d) of claim 43 as well as claim 47 is supported, for example, by the disclosure at page 6, line 20 to page 7, line 4; and page 8, line 13 to page 9, line 10. Clause e) of claim 43 as well as claims 48-50 are supported, for example, by the disclosure at page 7, line 18 to page 8, line 12. Furthermore, claims 51-52 and 54-55 are supported by the disclosure as filed for example by claim 6 and 9 as originally filed.

Applicants gratefully acknowledge allowance of claims 2 and 4-11.

Rejection Under 35 U.S.C. § 102(e)

Claim 3 stands rejected under 35 U.S.C. § 102(e), as allegedly anticipated by U.S. Patent No. 5,916,751 (Tabizadeh et al., "the '751 patent"). Applicants traverse the rejection. According to the Office Action, the '751 patent allegedly teaches a polynucleotide sequence that contains a region of 303 nucleotides that is 92% identical to SEQ ID NO:1 of the present application, complements of portions of SEQ ID NO:1, and regions of greater than 15 nucleotides that are identical to regions of SEQ ID NO:1 of the present application. Claim 3 has been cancelled without prejudice in the present amendment. Therefore, the rejection is moot, with respect to claim 3.

In addition, newly added claims 43-55 are also not anticipated by the '751 patent. Claims 43 and 53, from which the remainder of the newly added claims depend, are directed to an isolated polynucleotide that includes a nucleotide sequence encoding the growth differentiation factor-16

(GDF-16) polypeptide as set forth in SEQ ID NO: 2; a nucleotide sequence according to SEQ ID NO:1, wherein T can also be U; or a nucleotide sequence complementary to the entire nucleotide sequence of SEQ ID NO:1. As acknowledged in the Office Action, the '751 patent does not report the GDF-16 polypeptide of the present invention or a nucleotide sequence according SEQ ID NO:1. Therefore, the '751 patent does not anticipate claim 53 or clauses a, b, and c of claim 43.

Claim 43 also recites an isolated polynucleotide that includes a nucleotide sequence that is 98% identical to SEQ ID NO:1 and which encodes a protein having GDF-16 biological activity, and a fragment that is at least 50 nucleotides in length and at least 99% percent identical to SEQ ID NO:1, or a complement thereof. As acknowledged in the Office Action and illustrated by the BLAST search results shown in Exhibit A, which compare SEQ ID NO:1 of the present application with SEQ ID NO:1 of the '751 patent, the '751 patent does not report a polynucleotide that is at least 99% identical to SEQ ID NO:1 of the present application. Furthermore, as illustrated by the BLAST results of Exhibit A, the '751 patent does not report a fragment that is at least 50 nucleotides in length and at least 99% percent identical to SEQ ID NO:1, or a complement thereof. Therefore, the '751 patent does not anticipate newly added claim 43-55. Accordingly, Applicants respectfully request withdrawal of the rejection of claim 3 under 35 U.S.C. § 102(e).

Rejection Under 35 U.S.C. § 112, first paragraph

Claim 3 stands rejected under 35 U.S.C. § 112, first paragraph because it is alleged that the specification, while being enabling for SEQ ID NO:1, does not reasonably provide enablement for fragments that will detect sequences encoding GDF-16 by hybridization. The Office Action alleges that specific hybridization conditions are required because under low enough stringency any DNA will hybridize to any other. Claim 3 has been canceled by the present amendment. Therefore, the rejection is moot.

Furthermore, newly added claims 43 and 53, and the remainder of the newly added claims, which depend therefrom, do not recite hybridization requirements. Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

In re Application of:
Lee et al.
Application No.: 09/485,045
Filed: May 12, 2000
Page 7

PATENT
Attorney Docket No.: JHUI440-1

CONCLUSION

In summary, for the reasons set forth herein, claims 2, 4-11, and 43-55 clearly and patentably define the invention, and Applicants respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: August 30, 2002



Lisa A. Haile, J.D., Ph.D.
Registration No. 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133

USPTO Customer Number 28213

In re Application of:

Lee et al.

Application No.: 09/485,045

Filed: May 12, 2000

Exhibit A - Page 1

PATENT

Attorney Docket No.: JHU1440-1

EXHIBIT A

Polynucleotide BLAST sequence comparison of SEQ ID NO:1 of the present application
and SEQ ID NO:1 of U.S. Patent Number 5,916,751.